

mon or usual name of each such ingredient; and 403(k)—the article contained an artificial flavoring and it failed to bear a label stating that fact.

DISPOSITION: 4-1-64. Default—destruction.

29786. Vanilla concentrate. (F.D.C. No. 49910. S. No. 30-906 A.)

QUANTITY: 8 1-gal. btls. at Cincinnati, Ohio.

SHIPPED: 11-13-63, from Union City, N.J., by Reynaud, Ltd.

LABEL IN PART: (Btl.) "Reynaud, Ltd. Pure Vanilla 10-Fold Concentrate TK 503 Contains: Extractive Matter of Vanilla Beans * * * For Manufacturing Use Only * * * Union City, New Jersey."

LIBELED: 3-9-64, S. Dist. Ohio.

CHARGE: 402(b)(1)—when shipped, the valuable constituent of the article, vanilla extractives, had been in whole or in part omitted or abstracted; 402(b)(2)—vanillin and flavorings other than true vanilla extractives, had been in whole or in part substituted for the article; 402(b)(4)—vanillin and flavorings other than true vanilla extractives had been added to the article or mixed or packed therewith, so as to make it appear better or of greater value than it was; 403(a)—the label statement "Pure Vanilla 10-Fold Concentrate" was false and misleading since it was contrary to fact; 403(i)(2)—the article was fabricated from two or more ingredients and its label failed to bear the common or usual name of each such ingredient; and 403(k)—the article contained an artificial flavoring and it failed to bear a label stating that fact.

DISPOSITION: 3-23-64. Consent—delivered to a charitable institution for use as food for human consumption thereat, but not for sale or other use.

VITAMIN, MINERAL, AND OTHER PRODUCTS OF SPECIAL DIETARY SIGNIFICANCE*

29787. Various vitamin preparations. (F.D.C. No. 44376. S. Nos. 96-867/71 P.)

QUANTITY: 1 bulk can of 12,000 capsules and 11 100-capsule btls., 13 200-capsule btls., 2 100 capsule btls., and 5 200-capsule btls. of vitamins A and D; 1 bulk container of 20,000 capsules, 34 100-capsule btls., 39 200-capsule btls., and 4 500-capsule btls. of Natural B Complex; 22 ctns., 12 4-oz. btls. each, and 4 4-oz. btls. of brewers yeast; 122 100-tablet btls., 109 200-tablet btls., of Geriatric Gelly; 15 ctns., 12 50-tablet btls. each, and 15 50-tablet btls., and 1 100-tablet btl. of vitamin C at New York, N.Y., in possession of Charles Falkner, Inc., and in possession of the same firm, t/a Sunny-Health Foods.

SHIPPED: Between 4-30-57 and 1-12-60, (Natural B Complex and Geriatric Gelly) from Hoboken, N.J., by Willow Pharmacal Corp., and (other above-named articles) from Worcester, Mass., by Brewer & Co., Inc.

LABELS IN PART: (Btl.) "Falkner's 'Aydee' Formula Natural Vitamin A and D Capsules (from fish liver lipoids) In A Base of Pure Wheat Germ Oil Each Capsule provides: * * * Charles Falkner, Inc. Distr. New York 21, N.Y."; (btl.) "Falkner's Natural B Complex with Vitamin B-12 (2 mcg. Vitamin B-12 per capsule) Each capsule contains * * * Plus 2 mcg. of Vitamin B₁₂ per capsule for which Need in Human Nutrition has not yet been established. * * * Charles Falkner, Inc. Distr.—New York 21, N.Y."; (btl.) "Falkner's Super All-Natural B Concentrate (brewers yeast) Each teaspoonful contains the unknown as well as the known B-Complex Vitamins Found in 17.5 Gm.

*See also No. 29732.

or more of Brewers Yeast"; (btl.) "Falkner's Royal Geriatric Gelly An All-Natural High Potency Vitamin and Mineral With Addition of Royal Jelly 3307 Distributed by Charles Falkner, Inc." and (btl.) "Falkner's All-Natural Super Vitamin C, Bioflavonoids and Rutin * * * Each Capsule contains: Vitamin C 100 mg. (from Rose Hips) Citrus Bioflavonoids Complex (Hesperidin) 100 mg. Rutin 10 mg. (from Natural Sources) Charles Falkner, Inc. New York 21, N.Y."

ACCOMPANYING LABELING: Leaflets entitled "Falkner's Special Holiday Sale," "The Gift of Good Health," and "Falkner's Special Spring Sale," and a number of bottle labels for vitamin A and D capsules and Natural B Complex capsules.

RESULTS OF INVESTIGATION: The vitamin A and D capsules and Natural B Complex capsules in the bottles were repacked from bulk containers shipped as described above.

LIBELED: 3-25-60, S. Dist. N.Y.

CHARGE: Vitamin A and D capsules; 403(a)—while held for sale, the accompanying labeling contained the statement "with vitamin E to aid utilization of A and D," which was false and misleading since it was contrary to fact; and 403(j)—the article purported to be a food for special dietary use by reason of its vitamin content and its label failed to bear, as required by regulations, a statement of the amount of vitamin E present in the article.

Natural B Complex capsules, 403(a)—while held for sale, the label contained the false and misleading statement that the need for vitamin B₁₂ in human nutrition has not yet been established; and 403(j)—when shipped and while held for sale, the article purported to be a food for special dietary use by reason of its vitamin content and its label (bulk) failed to bear, as required by regulations, a statement of the proportion of the minimum daily requirement for vitamin B₁ and vitamin B₂ supplied by the article when consumed in a specified quantity during one day, and its label (bulk and repack) failed to bear, as required by regulations, a statement of all the vitamins and the amounts of the vitamin B complex present in the article.

Brewers yeast, 403(j)—when shipped, the article purported to be a food for special dietary use by reason of its vitamin content and its label failed to bear, as required by regulations, the statement "The need for pantothenic acid in human nutrition has not yet been established."

Geriatric Gelly, 403(a)—when shipped, the name "Royal Geriatric Gelly" was false and misleading since it represented the article to be royal jelly whereas the article consisted of numerous ingredients; and 403(j)—the article purported to be a food for special dietary use by reason of its vitamin content and its label failed to bear as required by regulations, a statement of the proportion of the minimum daily requirement for niacin supplied by the article when consumed in a specified quantity during one day.

Vitamin C tablets, 403(a)—while held for sale, the accompanying labeling contained false and misleading representations that citrus bioflavonoids in the article were biologically active; that they were the sources of essential vitamins, minerals, and amino acids; that they were most effective when combined with vitamin C; and that scientific investigations had established their importance in cellular metabolism and were essential throughout the entire life span from childhood to old age.

The libel alleged also that the vitamin A and D capsules, Natural B Complex capsules, brewers yeast, and Geriatric Gelly were misbranded under the provisions of the law applicable to drugs as reported in notices of judgment on drugs and devices, No. 7933.

DISPOSITION: 9-15-60. Consent—claimed by Charles Falkner, Inc., and relabeled.

29788. Kebex vitamin-mineral capsules. (F.D.C. No. 49882. S. Nos. 38-242/3 A.)

QUANTITY: 11 cases containing 24 50-capsule btl. each, 19 50-capsule btl., and 6 100-capsule btl., at Raymondville, Tex.

SHIPPED: Between 6-1-63 and 7-31-63, from Philadelphia, Pa., by Nutrition Research Laboratory.

LABEL IN PART: (Btl.) "Special Kebex Formula Vitamin Mineral Capsules Each capsule supplies * * * Dosage: * * * one or two capsules daily * * * Each capsule contains * * * Folic Acid, USP 0.5 mg. * * * Nutrition Research Laboratory Philadelphia, Pa."

LIBELED: 3-11-64, S. Dist. Tex.

CHARGE: 402(a)(2)(C)—when shipped, the article contained a food additive, folic acid, which was unsafe within the meaning of 409, since it and its use and intended use were not in conformity with a regulation or exemption.

DISPOSITION: 4-11-64. Default—destruction.

29789. Multi-vitamin solutions. (F.D.C. No. 49243. S. Nos. 65-828 V, 66-393 V.)

QUANTITY: 1,050 15-cc. btl., and 4,230 50-cc. btl., at Parsippany-Troy Hills, N.J.

SHIPPED. Between 9-20-62 and 9-29-62, from New York, N.Y.

RESULTS OF INVESTIGATION: Analysis showed that the 15-cc. btl. contained approximately 50 percent of the declared amount of vitamin A and approximately 75 percent of the declared amount of vitamin B₁, and that the 50-cc. btl. contained less than 79 percent of the declared amount of vitamin B₁.

LIBELED: 8-30-63, Dist. N.J.

CHARGE: 402(b)(1)—while held for sale, valuable constituents, vitamin A and (15-cc. btl. only) vitamin B₁, had been in part omitted or abstracted from the articles; and 403(a)—the label statements (15-cc. btl.) "Each 0.6 cc. contains Vitamin A 5000 USP Units * * * Vitamin B₁ 2 mg." and (50-cc. btl.) "Each 0.6 cc. contains * * * Vitamin B₁ 1.0 mg." were false and misleading as applied to products containing less than the declared amounts of these vitamins.

DISPOSITION: 12-10-63. Consent—destruction.

29790. Nuclomin tablets. (F.D.C. No. 49770. S. No. 58-361 X.)

QUANTITY: 6 cases, each containing 12 100-tablet btl., at Phoenix, Ariz.

SHIPPED: 11-22-63, from St. Louis, Mo., by Miller Laboratories, Inc.

LABEL IN PART: (Btl.) "69 100 Tablets Nuclomin Amino Acid Complexed Trace Minerals with Multi Vitamins * * * Dosage * * * two (2) to four (4) tablets per day with meals * * * Each two tablets contain: * * * Folic acid 0.2 mg. * * * Manufactured for and Distributed by Miller Laboratories, Inc. * * * St. Louis 3, Mo. for the Miller Pharmacal Co. West Chicago, Ill."

LIBELED: 2-3-64, Dist. Ariz.

CHARGE: 402(a)(2)(C)—when shipped, the article contained a food additive, folic acid, which was unsafe within the meaning of 409, since it and its use and intended use were not in conformity with a regulation or exemption.

DISPOSITION: 4-10-64. Default—destruction.